

**REMARKS**

The above amendments to the above-captioned application along with the following remarks are being submitted as a full and complete response to the Office Action dated September 8, 2004. In view of the above amendments and the following remarks, the Examiner is respectfully requested to give due reconsideration to this application, to indicate the allowability of the claims, and to pass this case to issue.

**Status of the Claims**

As outlined above, claims 1 to 24 have been canceled without prejudice or disclaimer in a previous communication with the office, while claims 25 – 28, 31, 32 and 35 are being amended to correct formal errors and to more particularly point out and distinctly claim the subject invention. It is submitted that no new matter is being introduced into the application through the submission of this response.

**Formal Objections or Rejections**

The Specification was objected to for failing to provide proper antecedent basis for the feature of the width of the bow shaped connector bar being 10 to 50% smaller than the width of a straight bar. The specification is being amended in accordance with the Examiner's requirements. Based on the above, withdrawal of the above objection is respectfully requested.

**Prior Art Rejections**

Claims 25 – 28, 33 – 35 and 45 were rejected under 35 U.S.C. §102(e) as being anticipated by Cox, U.S. Patent No. 6,461,380 B1 (further, Cox '380).

The present invention as recited in amended claim 25 is directed to A radially expandable intraluminal vascular support comprises a plurality of coupled flexible zigzag formed annular elements formed by straight bars of equal length and connected by arch portions therebetween, the zigzag annular elements being ordered vertically along a longitudinal axis, the zigzag formed annular elements define a proximal end and a distal end of the intraluminal vascular support, wherein each zigzag annular element is coupled to at

least one other annular element through at least one opposing pair of bending elements, each of the bending elements being formed from a bow shaped connector bar connected between arch portions of adjacent zigzag annular elements, wherein portions of said adjacent zigzag annular elements and said bow shaped bars connected therebetween are arranged to form corresponding star shaped segments.

Among the main features of the invention, the radially expandable intraluminal vascular support comprises stents with star shaped bending elements. The stent of the present application allows the opening to be widely opened at the site of the stent in a fully expanded state and allows the branch exits of the vessel system to stay completely opened. The highly flexible stent of the present invention can easily be bent in curved vessels in a collapsed state. In addition, applicants would submit that the star shaped elements of the invention allow for high flexibility, high permeability and high radial stability in expanded state.

Applicants have observed that most drawings illustrating stents, especially in patents, show the production state of a stent. For application into a vessel, the stent is mostly transferred onto a balloon and will be compressed. In its compressed state, the stent is transferred into a catheter. Later, in the vessel, the stent is expanded by dilatation of the balloon. Cox '380, in particular, shows a stent in its production state (See col. 2, lines 22 to 28).

In the production state, the stent of the present invention has clearly more space between its individual struts than the structure shown for the stent of Cox '380. This is due to the clear zigzag design of the annular elements, as opposed to the narrow serpentine design of Cox '380.

A critical point in stent applications is the compression of a stent from the production state into the compressed state on a balloon. The surface of the balloon tends to be squeezed between the bars and bows of the stent. With an open zigzag pattern according to the present invention, squeezing of the balloon between the struts of the stent and damage of the balloon is highly unlikely, because there is much more space available for the movement of the struts.

On the other hand, the pattern of the stent of Cox '380, in its production state, only has small dimensioned openings, which easily come into contact with each other upon compression. This is illustrated by comparing Figures 1, 2, 5a, 5b of the present application which illustrate the present invention with Figures 6a and 6b, which are relate to Figure 3 of Cox '380.

Moreover, focusing onto the fully expanded state of the stent of the present invention (See Figures 3, 5c), it can easily be seen that the star shaped openings of the production state open to form an approximately rhombic pattern.

Altogether, the stent of the present invention has more freedom to become compressed for application, without sacrificing the mesh like pattern of the expanded stent.

A further aspect of the present invention is the flexibility of the stent design. It is critical not to overstretch the bows upon expansion to avoid crack formation. The zigzag design clearly lowers the bending stress on the bows of the zigzag elements on expansion; Figures 5b and 5c show that the angle widening in the zigzag elements is limited. On the other hand, in Cox '380 the bars of the serpentine elements are all parallel. Upon expansion, the widening of the serpentine elements to the rhombic pattern is much more expressed, this increasing the probability of creating cracks at the inner radius of the bows (See Figures 6b and 6c). Even breakage of a bow in its apex is possible.

The same holds for the bow shaped connector bars of the present invention, which are located at the bows of the zigzag shaped annular elements. During expansion, bending forces are limited and therefore controlled. On the other hand, widening of the connector bows in Cox '380, and bending stress related thereto, is much more expressed.

The serpentine design of Cox '380 necessitates a specific arrangement of the serpentines in order to leave room for the connector bars. As a result, Cox has maximally extended apexes 74 and minimally extended apexes 76, and different lengths of the straight bars in the serpentine annular elements.

This specific design of the stent of Cox '380 results in a limited compressibility (See Figure 6b compared to Figure 6a). The maximum compression thus is D3 + D4. On the other hand, the zigzag design allows a greater compression (see Figure 5b compared to Figure 5a) of D1 + D2. In order to get expanded to its final stage, the Cox '380 stent has to be expanded to a greater extent than the stent of the present invention, with the consequence that the likelihood of crack formation in the regions under bending stress is much greater.

All the features and advantages discussed above are achieved by the structure of the present invention as now claimed. The reference of Cox '380 does not disclose, teach or suggest any such structure as now recited therein, nor does that reference achieve any of the

advantages of the claimed invention. Consequently, the present invention as now claimed is distinguishable and thereby allowable over Cox '380.

Claims 29 and 30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cox '380 in view of Klein, U.S. Patent No. 6,602,281 B1 (further, Klein '281).

Further, claims 31, 32, 36 and 37 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cox '380 in view of Richter, U.S. Patent No. 5,807,404 (further, Richter '404).

Even more, claims 38 to 44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cox '380 in view of Wright, U.S. Patent No. 6,273,913 B1 (further, Wright '913). Applicants have carefully considered each of these rejections, and hereby respectfully traverse.

As noted above, the present invention as claimed is distinguishable from the primary reference of Cox '380. Each of the secondary references noted above are merely cited for features recited in the dependent claims, and by themselves fall far short of providing any disclosure or suggestion that would make up for the deficiencies in Cox '380.

In particular, Klein '281, as shown in its Figures 2, 12 and 13, and discussed in col. 12, lines 55-76, teaches expandible serpentine rings with additional elements to increase radial stiffness. Fig. 13 further shows the maximal and distal end of a stent covered by annular sheets. Klein does not disclose stents wherein the width and/or the cross-section of the bow shaped connector bars is smaller in the middle section than at the ends.

Richter '404 discloses a stent (Fig. 1), wherein adjacent bows (C-shaped loops) are connected by flexible connector bows. The connector bows may be modified in strength. However, Richter '404 does not enable a stent having the star shaped segments of the present invention of the production state.

Wright '913 discloses a stent with struts having a generally uniform thickness and no particular shape for the annular elements or for the connection bars is specified.

In view of the foregoing, Applicants respectfully submit that none of the cited references discussed above, either by themselves or in combination with one another, can render each and every feature of the present invention as claimed obvious to one of skill in the art. Further, Applicants will contend that none of those references provides any disclosure, teaching or suggestion that would motivate their combination such that any

combination of those references could render the claimed invention obvious to one of skill in the art. Even if they were combined, those combinations would still fall short of showing or suggesting every feature of the present invention as recited in at least the independent claim 25. Consequently, the present invention as a whole is allowable over all the prior art references cited.

Conclusion

In view of all the above, Applicants respectfully submit that certain clear and distinct differences as discussed exist between the present invention as now claimed and the prior art references upon which the rejections in the Office Action rely. These differences are more than sufficient that the present invention as now claimed would not have been anticipated nor rendered obvious given the prior art. Rather, the present invention as a whole is distinguishable, and thereby allowable over the prior art.

Favorable reconsideration of this application as amended is respectfully solicited. Should there be any outstanding issues requiring discussion that would further the prosecution and allowance of the above-captioned application, the Examiner is invited to contact the Applicant's undersigned representative at the address and phone number indicated below.

Respectfully submitted,

Stanley P. Fisher  
Registration Number 24,344

Juan Carlos A. Marquez  
Registration Number 34,072

**REED SMITH LLP**  
3110 Fairview Park Drive  
Suite 1400  
Falls Church, Virginia 22042  
(703) 641-4200

**December 8, 2004**